UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH CAROLINA

COLUMBIA DIVISION

UNITED STATES OF AMERICA *ex rel.* **UNDER SEAL**	)	**Civil Action No.** 3:12-2011-CMC
v.	)	**FILED UNDER SEAL**
DEFENDANT UNDER SEAL	)	**JURY TRIAL DEMANDED**

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS
31 U.S.C. § 3729, ET SEQ.

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UNITED STATES DISTRICT COURT

DISTRICT OF SOUTH CAROLINA

COLUMBIA DIVISION

UNITED STATES OF AMERICA *ex rel.* [redacted]	)	
Plaintiff,	)	
v.	)	**Civil Action No.** 3:12-2011-CMC
ELI LILLY & COMPANY,	)	**FILED UNDER SEAL**
Defendant.	)	**JURY TRIAL DEMANDED**

TABLE OF CONTENTS

COMPLAINT FOR FALSE CLAIMS ACT VIOLATIONS, 31 U.S.C. § 3729, ET SEQ.

I. INTRODUCTION

1. This is an action to recover damages and civil penalties brought on behalf of the United States of America by [redacted] ("Relator [redacted]") by and through her attorneys, against Defendant Eli Lilly & Company ("Eli Lilly") pursuant to the *qui tam* provisions of the Federal Civil False Claims Act, 31 U.S.C. § 3729, *et seq.* for causing the submission of false or fraudulent claims to federal health care programs such as Medicaid, Medicare, and TRICARE ("Federal Programs").

2. From 2001 to present, Eli Lilly engaged in a fraudulent scheme to deceive and defraud patients, regulators, healthcare providers ("HCPs"), and Federal Programs by causing false and fraudulent claims for reimbursement of Teriparatide ("Forteo") to be presented to Federal Programs.

3. Eli Lilly's fraudulent promotion of Forteo across the United States included, *inter alia*, the following strategies:

a. Engaging in off-label marketing of Forteo.

b. Sponsoring and facilitating presentations by HCPs that promoted the off-label use of Forteo and providing these same HCPs with monetary kickbacks for leading peer-to-peer speaker programs on the off-label use of Forteo.

c. Sponsoring Managing Your Osteoporosis ("MYO") sessions, meant to educate patients on using the Forteo injectable, with Eli Lilly paid Nurse Educators who then promoted the off-label use of Forteo in their own practices and directed patients attending MYO sessions to Specialty Pharmacies.

d. Encouraging HCPs to direct patients to Specialty Pharmacies, rather than typical retail or mail order pharmacies, and using Specialty Pharmacies to capture and track data on specific patients and their compliance with their Forteo prescriptions as well as tracking specific HCPs' prescriptions for Forteo and determining whether those HCPs were providing an adequate "return on investment" – in violation of the False Claims Act and Federal Anti-Kickback Statute ("AKS").

e. Making unsubstantiated claims of superiority over other Osteoporosis drugs – primarily bisphosphonate drugs like Fosamax.

4. Eli Lilly's conduct caused false or fraudulent claims involving Forteo to be submitted to Federal Programs for uses that were not eligible for payment or reimbursement of any kind by these Federal Programs.

II. PARTIES

A. Plaintiff/Relator [redacted]

5. Relator [redacted] a resident of North Charleston, South Carolina. Relator [redacted] has been employed by Eli Lilly for 15 ½ years, from Nov. 14, 1996 through the present. Relator [redacted] holds a Bachelor of Arts degree in Business Administration/Marketing. Relator [redacted] current position as Eli Lilly is Executive Sales Specialist, MSK Osteoporosis Business Unit.

6. Relator [redacted] is an original source of the allegations in this Complaint, and she has provided the government with information prior to the filing of this Complaint pursuant to 31 U.S.C. § 3730(b)(2). There have been no public disclosures of the allegations or transactions contained herein that bar jurisdiction under 31 U.S.C. § 3730(e). Relator [redacted] makes these allegations based upon personal knowledge, discussions with Eli Lilly's representatives and relevant documents.

B. Defendant Eli Lilly & Company

7. Eli Lilly is an international pharmaceutical company and a corporation organized and existing under the laws of the state of Indiana with its principal place of business located at Lilly Corporate Center, Indianapolis, Indiana 46285. Eli Lilly is authorized to conduct business in South Carolina and all other states in the United States, and its registered agent for service of process is National Registered Agents, Inc., 2 Office Park Ct., Columbia, South Carolina 29223.

8. The acts alleged to have been done by Eli Lilly herein were authorized, ordered, done and/or ratified by Eli Lilly's officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction or Eli Lilly's business affairs.

III. JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this action pursuant to 31 U.S.C. § 3732(a), 28 U.S.C. § 1331, and 28 U.S.C. § 1345.

10. This Court has personal jurisdiction over Defendant Eli Lilly & Company because Eli Lilly transacts business in the District of South Carolina, and has engaged in wrongdoing in this District and throughout the United States. Namely, Eli Lilly did, individually or in conjunction with others, research, develop, manufacture, create, design, test, label, sterilize, package, distribute, supply, market, sell, promote, advertise, warn, and otherwise distribute Forteo in this District and throughout the United States.

11. This Court is the proper venue pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b), (c) because Eli Lilly transacts business in this District, and actions in violation of 31 U.S.C. § 3729, *et seq.* occurred in this District.

IV. ELI LILLY'S OFF-LABEL MARKETING OF FORTEO

A. Background on Forteo and Off-label Marketing

1. The Development of Forteo to Treat Osteoporosis

12. Forteo injections were approved in 2002 for the treatment of postmenopausal women with Osteoporosis who are at a high risk for fracture, and to increase bone mass in men with primary or hypogonadal Osteoporosis who are at high risk for fracture.

13. In July 2009, the FDA approved Forteo for use in treating Osteoporosis that is associated with sustained, systemic glucocorticoid (steroid) therapy in both men and women who are at a high risk for fracture.

2. FDA Approval and Off-Label Promotion and Misbranding

a. New Drug Approvals by the FDA

14. In order to receive approval for a new drug, pharmaceutical companies such as Eli Lilly must first conduct animal testing followed by an Investigational New Drug ("IND") application. 21 C.F.R. § 312.20(a) (West 2012).

15. This IND must include the investigational plan, all protocols for human studies, and the qualifications of all clinical investigators. *See* 21 C.F.R. § 312.23 (West 2012) (detailing the content and format of IND applications).

16. "The clinical investigation of a previously untested drug is generally divided into three phases. Although in general the phases are conducted sequentially, they may overlap." *Id.* § 312.21 (West 2012).

17. During Phase 1, the drug is administered to a small group of humans, typically twenty (20) to eighty (80) human volunteers, in order "to determine the metabolism and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness." *Id.* § 312.21(a).

18. During Phase 2, "well controlled" and "closely monitored" studies are conducted on a small subset of the target patient population in order "to determine the common short-term side effects, and risks associated with the drug." *Id.* § 312.21(b). Phase 2 studies typically include "no more than several hundred [human] subjects." *Id.*

19. "Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase 3 studies usually include from several hundred to several thousand [human] subjects." *Id.* § 312.21(c).

20. Only after a drug completes the IND process may the manufacturer submit a "New Drug Application" ("NDA") to the FDA. *See generally id.* § 314 (West 2012).

21. The NDA must include information about what the drug is composed of, any reactions that the drug may cause, the results of clinical studies (Phases 1-3), the risks and benefits of the drug, and a proposed copy of the label that will accompany the prescription drug. *Id.* § 314.50.

22. The pharmaceutical manufacturer must submit a proposed label for the drug with their NDA. *See generally id.* § 314. This label must not be misleading and must be updated when "new information becomes available that causes the labeling to become inaccurate, false, or misleading." *Id.* § 201.56(a) (West 2012). The label must include, *inter alia*, boxed warnings, indications and usage, dosage and administration, contraindications, warnings and precautions, adverse reactions, and drug interactions. *Id.* § 201.56(d) (West 2012).

23. After a pharmaceutical manufacturer has received approval for a new drug through the IND and NDA process, if they wish to alter the indications or the label of the drug, they must submit a supplementary NDA. *Id.* § 314.54. Unless and until the FDA subsequently approves any new use of a drug, any unapproved use is considered off-label.

24. Although the IND, NDA, and supplementary NDA process can be tedious, time consuming, and expensive, compliance with these requirements, as well as the statutory and regulatory

schemes related to off-label promotion and misbranding, ensure that the country's drug supply is safe.

b. Off-label Promotion and Misbranding

25. After approval, a drug may only be marketed and promoted for the indications that the FDA has approved in the drug manufacturer's NDA or supplemental NDA. Promotion or marketing for any other unapproved condition, duration, or dosage is considered "off-label" promotion.

26. The FDA approval process does not approve a drug for treatment of sickness in general.

27. Some off-label uses of drugs are accepted in the medical community, while others may prove dangerous to patients. For this reason, doctors are permitted to write off-label prescriptions if they choose to do so within their best medical judgment, but pharmaceutical sales representatives and employees are not permitted to market a drug to physicians and other HCPs for off-label indications, at off-label dosages, or for off-label durations.

28. Although off-label prescriptions are typically acceptable under the Food, Drugs, and Cosmetics Act ("FDCA") when written by a HCP in their best medical judgment, drug companies are restricted from disseminating information about off-label uses and reimbursement of HCPs for off-label uses by Federal Programs is also restricted.

29. The FDA has further noted that allowing pharmaceutical companies and manufacturers to promote off-label uses of a drug would pose a threat to the safety of the population and would weaken the clinical and scientific research that pharmaceutical companies conduct to ensure that a drug is safe. Therefore, the off-label regulatory scheme preventing pharmaceutical companies from disseminating off-label information protects patients and consumers by prohibiting drug companies from promotion of products for uses other than those found safe and effective.

30. Accordingly, off-label information can only be distributed at the request of a physician or HCP and may not be disseminated by pharmaceutical sales representatives or other employees involved in the marketing of the drug. Manufacturers such as Eli Lilly may not directly or indirectly market or promote a drug for use that has not been approved by the FDA.

B. Eli Lilly's Fraudulent Off-label Marketing of Forteo

31. From 2001 to present, Eli Lilly has directed its employees and sales representatives to engage in the systematic and illegal off-label marketing of Forteo for unapproved conditions and durations.

32. Eli Lilly encouraged sales representatives to use "creative & innovative initiatives to meet business objectives" – primarily through the false and fraudulent off-label marketing scheme that Eli Lilly began in 2001.

33. Eli Lilly promoted Forteo to HCPs based on patient conditions and symptoms, such as back pain, height loss, and Kyphosis, rather than the FDA approved indication for which it was approved. This allowed Eli Lilly to greatly increase the number of HCPs that Forteo was marketed to and mirrored the Zyprexa marketing tactic of creating a market for a drug where one was thought not to exist and driving up the numbers of off-label prescriptions. Zyprexa is a second generation atypical antipsychotic drug manufactured and promoted by Eli Lilly.

34. Eli Lilly directed sales representatives to "Redefine FORTEO" and to redefine what "high risk for Osteoporosis" means in order to encourage HCPs to prescribe Forteo to patients with independently benign conditions and symptoms such as back pain, height loss, and smoking, and to increase the number of off-label prescriptions.

35. Eli Lilly specifically instructed that sales representatives "don't talk osteoporosis" and instead focus on the above mentioned patient conditions and symptoms rather than Forteo's approved, on-label indication.

36. For example, on May 2, 2003, Relator [redacted] District Manager, Greg Gerrald, suggested that sales representatives "[u]se 2-3 vivid patient descriptors, e.g., Height loss of > 2 inches[;] Loose, or poorly fitting clothes due to kyphosis[;] [or] Possible back pain" despite the fact that Forteo is not approved for any of these conditions or symptoms.

37. Most striking, Eli Lily directed that HCPs and their staff screen for potential Forteo patients by measuring their height and comparing it to the height listed on the patient's driver's license and considering a patient for Forteo if their current height is more than 2 inches less than the height listed on their driver's license – in essence basing an important diagnosis and prescribing a potentially dangerous drug based solely off of what the patient reported their height to be at the Department of Motor Vehicles. This program was known as the "Ht [height] loss/urgency campaign."

38. HCPs were also encouraged by Eli Lilly to conduct a VFA ("Vertebral Fracture Assessment") that considered various risk factors for fractures, according to Eli Lilly, including height loss, radiation therapy, small stature, eating disorders, and smoking – none of which are FDA approved indications for Forteo. These VFA programs were reimbursed by Medicare at $43.87 and included assessing osteoporosis based on "corticosteroid use," even though Forteo did not have a glucocorticoid indication until July 2009.

39. Eli Lilly also directed sales representatives to employ Account Based Selling ("ABS"), which was a marketing strategy launched in 2005 in order to get office staff to flag patients with

back pain and other symptoms for Forteo therapy. This ABS strategy, also known as the "Total Office" approach, continued from 2005 to the present.

40. Eli Lilly also focused on the "anabolic" features of Forteo and how it was good for fracture healing. Sales representatives were encouraged to discuss the mechanism of action ("MOA") of Forteo in order to induce HCPs to request Medical Letters dealing with fracture healing. In fact, Eli Lilly focused their sales tactics on nursing homes in 2011 in order to drive up the sales of Forteo for off-label uses - primarily fracture healing because "[a]pproximately 50% of long-term care (LTC) patients will fall annually" according to Eli Lilly.

41. Eli Lilly also instructed sales representatives to use **patient profiles** to emphasize these targeted symptoms in order to induce HCPs to prescribe Forteo for off-label uses. These patient profiles focused on non-approved conditions and symptoms rather than promotion of the drug based on the on-label indication.

42. Eli Lilly directed sales representatives to "humanize" patients by using these patient profiles in order to expand Forteo's use outside of its approved indication.

43. Patient profiles included "Bev" – a patient who "[e]xperiences acute back pain," "[t]hinks she's getting shorter; clothes don't fit well anymore," "[h]as chronic obstructive pulmonary disease," "[h]as lost 2 inches in height and has a vertebral fracture," and "[h]as used 5 mg/day prednisone for the past year and a half." This patient profile enabled sales representatives to market Forteo to pulmonologists and physiatrists who were alerted to the other symptoms in the profile such as "acute back pain."

44. Eli Lilly even used a patient profile of "Florence" in 2011 in order to exploit the fact that she was on Medicare Part D and had coverage for Forteo.

45. In order to accomplish this expanded Forteo market, Eli Lilly directed sales representatives to pattern their sales tactics after those used by Zyprexa sales representatives and to "[c]onsider the efforts required by Zyprexa to create the market with PCPs [Primary Care Physicians] that was thought to be for psychiatrists."

46. In addition to mirroring the sales tactics of Zyprexa sales representatives in order to expand Forteo into the PCP market, Eli Lilly directed sales representatives to use a "CME-like approach" in order to "create the urgency to treat."

47. In fact, Eli Lilly stated in 2005 that "PCPs are the growth engine for FORTEO" and that "[r]oughly 85% of PCP targets have yet to try FORTEO." In fact, Eli Lilly recommended that a checklist should be given to PCPs who could then give the checklist to patients in their PCP practice who would check off reasons [off-label symptoms such as back pain] "why they need FORTEO; patient therefore *sells herself* to be on therapy."

48. As is demonstrated below, Eli Lilly pled guilty to the off-label promotion and misbranding of Zyprexa in 2009, and because Forteo sales representatives mirrored the sales techniques of Zyprexa sales representatives prior to 2009, many of the same behaviors outlined in the Zyprexa Guilty Plea and Corporate Integrity Agreement occurred with the marketing of Forteo as well.

49. Eli Lilly sales representatives also encouraged HCPs to request Medical Letters prepared by Eli Lilly employed HCPs on various off-label uses of Forteo even though off-label information can only be distributed at the request of a physician or HCP and may not be disseminated by pharmaceutical sales representatives or other employees involved in the marketing of the drug. In fact, Eli Lilly encouraged sales representatives to "[a]lways offer to request a follow up Medical Letter" in response to questions or discussions about the off-label use of Forteo.

50. Eli Lilly sales representatives were trained and directed to solicit and encourage off-label promotion of Forteo and to provide HCPs with medical and scientific publications concerning off-label use of Forteo. Pursuant to 21 C.F.R. §§ 99.101-99.105, a manufacturer may only disseminate off-label information in response to an "unsolicited request from a health care practitioner."

51. The topics of these Medical Letters included, *inter alia*:

- Using Forteo for glucocorticoid induced Osteoporosis prior to the FDA indication for this condition (which was approved in July 2009).
- Eli Lilly used circular logic to report, in 2002, seven years prior to the glucocorticoid indication, that "Forteo is not **contraindicated** for use in patients with glucocorticoid-induced osteoporosis."
- Using Forteo for back pain.
- Using Forteo for fracture healing.

52. Despite the fact that the Forteo label included a "Black Box Warning" (the strongest warning the FDA can require) that Forteo was associated with Osteosarcoma in rats in clinical trials, Eli Lilly directed sales representatives to solicit requests from HCPs in order to disseminate Medical Letters that contradicted the Black Box warning and stated that there was not a risk of Osteosarcoma in humans despite a lack of evidence to support these conclusions.

53. In fact, Eli Lilly reported that "[t]he relevance of these [osteosarcoma] findings to humans is uncertain" and "[a]n external advisory committee . . . concluded that the rat findings were unlikely to predict the development of bone tumors in patients who receive Forteo." These statements were inapposite to the Black Box warning that the FDA determined needed to be on the Forteo label, and in fact directly contradicted the warnings set forth in that Black Box warning.

54. This off-label marketing strategy directly caused HCPs to prescribe Forteo for unapproved uses, and caused false and fraudulent claims for payment and/or reimbursement of these

claims to be presented to various Federal Programs. The off-label marketing strategies were created to generate overutilization of Forteo for conditions for which Forteo was not indicated and proven to be safe and effective or medically necessary.

C. Eli Lilly Knew the Legal Risks Related to Off-label Promotion of Forteo

1. Evista Guilty Plea

55. Eli Lilly was well aware of the legal risks inherent in the unlawful marketing and promotion of its prescription drug products. In December 2005, Eli Lilly agreed to enter into a guilty plea to a criminal charge in an Information filed by the Department of Justice. Eli Lilly entered into the plea agreement in connection with allegations that it engaged in illegal off-label marketing of its drug product Evista. The Information specifically charges that:

"Lilly executed its illegal conduct using a number of tactics, including:

- One-on-one sales pitches by sales representatives promoting Evista to physicians about off-label uses of Evista. Sales representatives were trained to prompt or bait questions by doctors in order to promote Evista for unapproved uses;
- Encouraging sales representatives promoting Evista to send unsolicited medical letters to promote the drug for an unapproved use to doctors on their sales routes;
- Organizing a 'market research summit' during which Evista was discussed with physicians for unapproved uses, including reducing the risk of breast cancer; and
- Creating and distributing to sales representatives an 'Evista Best Practices' videotape, in which a sales representative states that 'Evista truly is the best drug for the prevention of all these diseases' referring to osteoporosis, breast cancer, and cardiovascular disease."

Eli Lilly and Company to Pay U.S. $36 Million Relating to Off-Label Promotion, DOJ Press Release, December 21, 2005.

56. The Evista Plea Agreement expressly incorporates measures aimed at prohibiting Eli Lilly from future promotion of its products for off-label uses including, *inter alia*, "agree[ing] to hire and utilize an independent organization to conduct reviews to assist Lilly in assessing and

evaluating Lilly's systems, processes, policies, and procedures relating to the promotion of Evista and the company's compliance with the consent decree." *Id.*

57. While Eli Lilly was clearly aware of its compliance obligations regarding sales and marketing of its products, Eli Lilly senior sales, marketing, and corporate executives did everything they could to get around any such limitations in order to sell Forteo.

2. Zyprexa Guilty Plea and Corporate Integrity Agreement

58. In 2009, Eli Lilly entered into a Corporate Integrity Agreement ("CIA") with the United States Department of Justice related to its off-label marketing of Zyprexa

59. This CIA required Eli Lilly to institute, *inter alia*, many internal Complaince programs related to the marketing and promotion of pharmaceutical products.

60. Eli Lilly also entered into a Guilty Plea Agreement on January 14, 2009 due to its misbranding and illegal promotion of Zyprexa between September 1999 and March 31, 2001 – a time period that immediately preceded, and included, the preparations for the launch of Forteo.

61. The Guilty Plea and CIA came as a result of a Federal investigation and an Information that was subsequently filed against Eli Lilly.

62. The Information alleged that Eli Lilly "directed its sales personnel to promote Zyprexa for off-label uses" including "agitation, aggression, hostility, dementia, Alzheimer's dementia, depression, and generalized sleep disorder," none of which were approved indications for Zyprexa.

63. "In October 2000, ELI LILLY began this off-label marketing campaign targeting primary care physicians, even though ELI LILLY knew that there was virtually no on-label use for Zyprexa in the primary care market."

64. Additionally, the Information alleged that Eli Lilly "created patient profiles for the sales force to use to promote Zyprexa in this [PCP] market" which allowed Eli Lilly sales representatives to market Zyprexa to *symptoms* of psychotic disorders and Schizophrenia – such as anxiety and difficulty sleeping – rather than for the FDA approved indications.

65. Finally, the Information alleged that Eli Lilly "retained medical professionals to speak to doctors during peer-to-peer sessions about off-label uses of Zyprexa" and "specifically trained its sales representatives on how to respond to doctors' concerns about off-label uses of Zyprexa, and how to continue to promote Zyprexa for off-label indications."

66. As a result of the Information and Guilty Plea, Eli Lilly was required to pay a total criminal penalty of $615 million ($515 million as a criminal fine and $100 million as a criminal forfeiture).

67. This $515 million criminal fine was, at the time, "the largest criminal fine in a healthcare matter and the largest criminal fine paid by an individual defendant in the history of the Department of Justice for violation of any criminal statute."

68. One of the attorneys for the Department of Justice noted at the hearing on the Criminal Plea Agreement that "this is not the first time that Eli Lilly has violated the Food, Drug, and Cosmetic Act. **Eli Lilly is a recidivist**." ("Transcript of Hearing, January 30, 2009" at 17:9-11).

69. Forteo sales representatives employed the same tactics as Zyprexa sales representatives – including targeting primary care physicians, marketing Forteo for symptoms rather than FDA indicated conditions, and paying HCPs to give peer-to-peer talks promoting the off-label use of Zyprexa.

70. The problems outlined in the Zyprexa Information, Criminal Plea Agreement, and CIA were not unique to Zyprexa and permeated other divisions, and in fact were promoted by the leadership of Eli Lilly.

71. While Eli Lilly was clearly aware of its compliance obligations regarding sales and marketing of its products, Eli Lilly senior sales, marketing, and corporate executives did everything they could to get around any such limitations in order to sell Forteo.

V. ELI LILLY PAID KICKBACKS TO PHYSICIANS AND OTHER HCPS TO INDUCE THEM TO PRESCRIBE AND RECOMMEND FORTEO

72. From 2001 to present, Eli Lilly planned and implemented CME-like speaker programs in order to improperly influence HCPs' prescribing habits and to encourage them to prescribe Forteo for off-label uses. These CME-like speaker programs were not independent of Eli Lilly and instead were dominated by Eli Lilly's influence and bias.

73. As early as 2001, prior to FDA approval of Forteo for any indications, Eli Lilly had already directed sales representatives and district managers to target HCPs in the region for speaking programs. These HCPs in Relator [redacted] district included Dr. T. Ken Gray, an Endocrinologist who was described as "almost evangelistic in speaking style." In fact, Relator [redacted] District Manager determined that Dr. Gray should be "elevated to PTH [Parathyroid Hormone] Advisory Board status." Sales representatives were further instructed to create "opportunities that do not currently exist to access MDs."

74. For example, ten lunch or dinner programs were held in the Columbia, SC region during the 4th Quarter of 2001, costing a total of $19,050. These lunch and dinner programs included at least one Eli Lilly funded speaker.

75. In fact, Eli Lilly targeted what they termed the "Forteo Five" – a collection of five doctors who were targeted for the speaker programs (Drs. Vargo, Mendelsohn, Nankin, Lawson, and Dodd).

76. The Charleston territory instituted a "Train the Trainer" program where they paid a "top MD" in the area $500 to speak to physicians in the area to discuss Forteo (including potential off-label uses for Forteo).

77. Eli Lilly instructed sales representatives to identify and "develop" potential speakers by reviewing material on Forteo with the HCP while playing golf or at dinner in order to certify them as a "Lecturer."

78. HCPs from specialties that would not typically treat patients with Osteoporosis were also targeted – such as Dr. John Knab and Dr. Jeff Wilkins, both pain management specialists/Physiatrists. Dr. Wilkins was an Eli Lilly speaker and was reported to be an "advocate of Forteo, [and it's] experience with pain relief." In fact, Dr. Wilkins worked both as a Physiatrist in Conway, SC and a Medical Director for Acute Rehab at Waccamaw Hospital in Murrell's Inlet, SC. This enabled Eli Lilly to leverage its relationship with Dr. Wilkins to encourage the off-label prescribing of Forteo for fracture healing and pain management.

79. Many Forteo speakers were known to Eli Lilly to have given speeches and conducted CMEs in the past that promoted other Eli Lilly drugs, such as Evista, for off-label uses.

80. Eli Lilly's targeting of physicians for speaker programs contradicted their own express policy that: "Any type of activity that could be viewed as industry influence or promotion around a CME program risks FDA enforcement."

81. Eli Lilly also directed sales representatives to track the return on investment ("ROI") of these speaker programs to determine if the speaker program caused HCPs in attendance to pre-

scribe Forteo for off-label uses (and to track the prescribing habits of the speaker) – constituting an impermissible *quid pro quo*.

82. For example, Eli Lilly used its relationship with Specialty Pharmacies, outlined below, to instruct sales representatives to run weekly queries to determine if Eli Lilly funded speaker programs had an impact on specific HCPs' number of Forteo prescriptions written.

83. Eli Lilly instructed sales representatives to "[r]un queries weekly to measure impact and to see if the program impacted the physician" as well as to "TRACK RETURN ON INVESTMENT."

84. Additionally, Eli Lilly paid Nurse Educators to lead MYO programs to instruct patients on the use of the Forteo injectable. In fact, Eli Lilly directed sales representatives to leverage their relationships with MYO Educators, who were paid by Eli Lilly, in order to have the Nurse Educators screen for potential Forteo candidates for off-label use (e.g., based on symptoms and patient profiles) in their own practices. These MYO sessions were often held in various HCP offices and other locations throughout the country.

85. These MYO Educators and other HCP office staff were encouraged by Eli Lilly sales representatives to use the "Osteoporosis Candidate Clip-Board" Program in order to get HCPs to screen incoming patients for non-approved conditions and symptoms (i.e. back pain, height loss, and Kyphosis) in order to increase the number of off-label prescriptions for Forteo. Eli Lilly suggested that sales representatives have nurses or office staff "place a sticker on the triage page of patients with back pain, height loss, or a kyphosis hump."

86. Eli Lilly sales representatives were encouraged to identify "office champs" – MYO Educators or other HCP office staff who flagged prospective Forteo patients.

87. As an example of the extent of these peer-to-peer speaking programs, Eli Lilly spent $8.2 million on Forteo Promotional Programs in 2010. Eli Lilly then directed employees to calculate the return on investment for Promotional Programs in 2009. The return on investment for 2009 was calculated to be -18% - certainly giving sales representatives an incentive to encourage and coach speakers to present on new uses for Forteo that are not FDA approved.

88. Sales representatives were rewarded for being successfully in instituting MYO programs and having high volumes of patients as well as for finding the ideal Nurse Educator for their MYO programs (who would be "coachable" according to Eli Lilly) through Eli Lilly's "Shoot Em Up" program which rewarded sales representatives and Eli Lilly employees for holding large numbers of MYO programs.

89. These MYO Educators had a clear financial incentive to influence fellow HCPs and office staff to screen and recommend patients for Forteo, which would allow the MYO Educator to receive greater remuneration for coaching a large number of patients. In fact, Eli Lilly directed sales representatives to "point out 'what is in it for her [MYO Educator].' "

90. Some MYO Educators like Harriet (Heidi) Mohn of Fayetteville, NC completed as many as 134 MYO programs for Eli Lilly – benefitting financially from teaching each program.

VI. ELI LILLY ENGAGED IN AN UNLAWFUL BUSINESS RELATIONSHIP WITH SPECIALTY PHARMACIES THAT VIOLATED THE FEDERAL ANTI-KICKBACK STATUTE

91. Eli Lilly instructed sales representatives to encourage HCPs and their office staffs to direct patients to various Specialty Pharmacies, which provide mail order prescriptions and other services such as a help line for patients, rather than other retail or mail order pharmacies.

92. Eli Lilly referred to this relationship with Specialty Pharmacies as a "special gift" and a "growth area" for Forteo business.

93. Though Eli Lilly's stated policy was that "Lilly sales representatives should not promote one pharmacy over another" and have "no conversations in which a pharmacy preference is stated," Eli Lilly instructed its sales representatives to do exactly these two things.

94. Eli Lilly sales representatives were instructed to leave "leave behind" brochures that promoted Specialty Pharmacies over other retail and mail order pharmacies with HCPs and their office staff. These brochures contained statements such as: "Although any retail pharmacy can dispense FORTEO® (teriparatide [rDNA origin] injection), a Specialty Pharmacy offers additional services that provide the patient with counseling, injection-training support, and added convenience."

95. Eli Lilly also directed sales representatives to make similar statements directly to HCPs such as: "Doctor, although any pharmacy can dispense FORTEO, it is also available through Specialty Pharmacies. This will help your office with insurance investigation and prior authorization. More important [sic], Specialty Pharmacies offer patient benefits of 24/7 support, deliver to their home, free needles and swabs, and compliance monitoring. All it takes is for your office to fill out this simple, 1-page form."

96. Furthermore, Eli Lilly sales representatives left one page forms containing the information for the local Specialty Pharmacy with HCPs so that they could then sign the form and fax it to the Specialty Pharmacy. After receiving the form, the Specialty Pharmacy would then contact the patient and arrange for delivery of the patient's Forteo prescription. This process limited the choices that a patient had in selecting a pharmacy (retail, mail order, or Specialty) and increased the volume of Forteo prescriptions that Specialty Pharmacies were filling. In return, Specialty Pharmacies helped Eli Lilly sales representatives track patient compliance and HCP prescriptions written which constituted an impermissible kickback.

97. Eli Lilly also directed sales representatives to leverage their relationships with MYO Educators in order to have the MYO Educators promote Specialty Pharmacies to patients at MYO sessions.

98. Information about Specialty Pharmacies was also added to the Forteo.com website in 2007.

99. Quite pointedly, one of the September 2007 Columbia District goals was to "[g]row FORTEO through targeted focused execution" and "[b]ack-end selling focus while implementing Spec.Phcy [Specialty Pharmacies]."

100. Although Eli Lilly disseminated a message in February 2006 that sales representatives should "[n]ever complete, handle or submit a PA [Prior Authorization] form . . . [and] should never be exposed to patient level information," by establishing this relationship with Specialty Pharmacies wherein Eli Lilly directed patients to Specialty Pharmacies rather than letting the patient make an independent and informed decision regarding where they would fill their prescription for Forteo, Eli Lilly was able to capture and track specific patient data and determine how many patients were filling their Forteo prescriptions and to "recapture" those patients that stopped filling their Forteo prescriptions.

101. For example, at the July 2006 District Meeting, the Asheville Territory presented slides that stated that one of their goals was to institute an "[i]nitiative that Specialty Pharm runs a list of pts. [patients] [t]hat have discontinued their Forteo Therapy. Have the Docs/office champ ask the specialty Pharmacies for a list of these patients so they know which patients are not compliant."

102. Eli Lilly's promotion of Specialty Pharmacies over other pharmacies continued over many years, and Eli Lilly instructed sales representatives to "[m]ake sure they [offices]

have NEW Check in forms, PharmaCare [referring to Specialty Pharmacies forms]." This constituted a per se endorsement of PharmaCare and other Specialty Pharmacies by Eli Lilly employees, in direct contradiction to their stated policy of not preferring one pharmacy over another.

103. Eli Lilly's relationship with Specialty Pharmacies violated the Federal Anti-Kickback Statute ("AKS"), discussed below, and allowed Eli Lilly to receive a benefit in the form of tracking patients and their compliance with Forteo in return for directing business to Specialty Pharmacies.

VII. ELI LILLY MADE UNSUBSTANTIATED CLAIMS OF SUPERIORITY OVER OTHER OSTEOPOROSIS DRUGS – PRIMARILY BISPHOSPHONATE DRUGS LIKE FOSAMAX

104. As early as 2002 and 2003, Eli Lilly disseminated information to be used by sales representatives to demonstrate the superiority of Forteo compared to other Osteoporosis drugs, primarily bisphosphonates such as Fosamax, despite the fact that there were no studies at the time directly comparing the efficacy of Forteo and Fosamax.

105. For example, Eli Lilly provided sales representatives with the following statement in 2002: "While there are no head-to-head studies comparing Forteo and alendronate [Fosamax] . . . [i]n terms of numbers needed to treat, data shows Forteo prevents a vertebral fracture for every 11 patients treated. Alendronate, [sic] prevents a vertebral fracture for every 35 patients treated."

106. Similarly, in 2003, Eli Lilly provided sales representatives with the following suggested statement for HCPs: 'Doc, when you think of pts. [patients] at high risk for fx [fracture]…you want a medication that works fast…in 19mos [19 months] an increase of 11.8% with Forteo as compared to bisphosphonates."

107. Eli Lilly also commissioned a Medical Letter that made unsubstantiated claims of superiority and stated that Forteo was superior to other Osteoporosis drugs, primarily bisphos-

phonates such as Fosamax, and sales representatives were instructed to elicit requests for this Medical Letter from HCPs even though Medical Letters are only supposed to be distributed in response to *unsolicited* questions by HCPs.

VIII. THE FEDERAL HEALTH CARE PROGRAMS

A. Medicaid

108. Medicaid is a joint federal and state program that was created in 1965 so that states could receive federal financial assistance if they chose to reimburse certain medical costs for needy individuals.

109. States are not required to participate in the Medicaid program, but if they choose to, they must abide by the Medicaid requirements.

110. In order to be eligible for federal assistance under the Medicaid program, a state must have a plan for medical assistance that has been approved by the Secretary of Health and Human Services. 42 U.S.C.A. § 1396a(a) (West 2012).

111. When a state's plan is approved by the Secretary of Health and Human Services, individual states then administer the various medical assistance programs under the Medicaid umbrella and the federal government provides grants to those states to reimburse them for medical services provided. *Id.*

112. Whether a drug is FDA-approved for a particular indication will, in large part, determine whether a prescription for that use will be reimbursed by the Medicaid program.

113. Medicaid typically only reimburses "covered outpatient drugs." 42 U.S.C.A. § 1396b(i)(10) (West 2012).

114. "Covered outpatient drugs" only includes drugs approved for a specific indication by the FDA or listed in one of several drug compendia listed in the Medicaid statute. *See* 42

U.S.C.A. § 1396r-8(g)(1)(B)(i) (West 2012) (listing the compendia that may be consulted under this statute).

115. Therefore, Medicaid reimbursements are only appropriate for off-label uses of a drug that are listed in one of the compendia referenced at 42 U.S.C.A. § 1396r-8(g)(1)(B)(i).

116. Eli Lilly marketed Forteo for off-label uses, detailed below, that should not have been reimbursed by Medicaid because they were not listed on the product label as an approved FDA indication and were not listed in any of the relevant compendia.

B. Medicare

117. The federal Medicare program is divided into five parts and reimburses HCPs for medical services provided to eligible patients.

118. Part A covers medical services provided in hospitals and other institutions

119. Part B is an optional and supplemental program that covers items and services that are not covered under Part A (e.g. outpatient services and lab tests).

120. Part C created the "Medicare + Choice" program which is an alternative to the coverage under Part A.

121. Part D creates a prescription drug benefit program for Medicare patients.

122. Part E covers other "Miscellaneous Provisions."

123. Similar to the Medicaid program, Medicare does not provide coverage for off-label uses of pharmaceutical drugs under Part D unless they are listed in one of the three medical compendia listed referenced above in the Medicaid regulations. *See* 42 U.S.C.A. § 1395w-102(e) (West 2012).

124. Eli Lilly marketed Forteo for off-label uses, detailed below, that should not have been reimbursed by Medicare because they were not listed on the product label as an approved FDA indication and were not listed in any of the relevant compendia.

C. TRICARE

125. TRICARE is a health care program that provides medical and pharmaceutical benefits to military personnel, veterans, and dependents of military personnel and veterans. *What is TRICARE?*, TRICARE MEDIA CENTER, http://www.tricare.mil/mediacenter/press_facts.aspx.

126. As of December 2011, there were 9.7 million TRICARE Eligible Beneficiaries nationwide. *Id.*

127. As of December 2011, 242,227 of these Eligible Beneficiaries were located in South Carolina – comprising 2.5% of all Eligible Beneficiaries nationwide. *TRICARE Resources*, TRICARE MEDIA CENTER, http://www.tricare.mil/mediacenter/press_state.aspx.

128. Of these 9.7 million total TRICARE Eligible Beneficiaries, there were approximately 5.9 million Enrolled Users nationwide as of December 2011. *What is TRICARE?*, TRICARE MEDIA CENTER, http://www.tricare.mil/mediacenter/press_facts.aspx.

129. TRICARE processed approximately 2.6 million prescriptions a week during calendar year 2011. *Id.*

130. Under TRICARE, coverage for off-label prescriptions is restricted by TRICARE guidelines and Federal regulations. *See, e.g.*, 32 C.F.R. § 199.4(g)(15) (West 2012).

131. TRICARE "can only cost-share medically necessary supplies and services. Any drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established is unproven and cannot be cost-shared by CHAMPUS [former name for TRICARE] except as authorized under paragraph 199.4(e)(26)." *Id.* The exception mentioned at paragraph

199.4(e)(26) is not relevant in this case as it only applies to clinical trials "sponsored or approved by the National Institutes of Health National Cancer Institute." *See id.* § 199.4(e)(26) (West 2012).

132. A drug is unproven for purposes of TRICARE coverage:

> (A) If the drug or device cannot be lawfully marketed without the approval or clearance of the United States Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient.
> . . .
> (B) Unless reliable evidence shows that any medical treatment or procedure has been the subject of well-controlled studies of clinically meaningful endpoints, which have determined its maximum tolerated dose, its toxicity, its safety, and its efficacy as compared with standard means of treatment or diagnosis.
> . . .
> (C) If reliable evidence shows that the consensus among experts regarding the medical treatment or procedure is that further studies or clinical trials are necessary to determine its maximum tolerated doses, its toxicity, its safety, or its effectiveness as compared with the standard means of treatment or diagnosis.

Id. §§ 199.4(g)(15)(i)(A), (C), (D) (West 2012). For purposes of the above quoted regulations, the Code of Federal Regulations defines "reliable evidence" as "(i) [w]ell controlled studies of clinically meaningful endpoints, published in refereed medical literature. (ii) [p]ublished formal technology assessments. (iii) [t]he published reports of national professional medical associations. (iv) [p]ublished national medical policy organization positions; and (v) [t]he published reports of national expert opinion organizations." *Id.* § 199.2 (West 2012).

133. Accordingly, TRICARE can

> Consider coverage of unlabeled or off-label uses of drugs that are Food and Drug Administration (FDA) approved drugs that are used for indications or treatments not included in the approved labeling. Approval for reimbursement of unlabeled or off-label uses *requires* review for medical necessity, and also requires demonstrations from medical literature, national organizations, or technology assessment bodies that the unlabeled or off-label use of the drug is safe, effective[,] and in accordance with nationally accepted standards of practice in the medical community.

Id. § 199.4(g)(15) (emphasis added).

134. Eli Lilly marketed Forteo for off-label uses, detailed below, that should not have been reimbursed by TRICARE because the off-label purposes were "unproven" and lacked "reliable evidence" according to the applicable Federal regulations.

D. Federal Anti-Kickback Statute

135. All persons and entities, including Eli Lilly and other pharmaceutical companies, are prohibited from engaging in any behavior that violates the Federal AKS. 42 U.S.C.A. § 1320a-7b(b) (West 2012). This law was enacted to prohibit payments that may influence health care decisions and to protect the integrity of the federal health care programs.

136. The AKS prohibits all persons and entities from knowingly and willfully accepting any form of payment or remuneration "in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program" or "in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program." *Id.* §§ 1320a-7b(b)(1)(A), (B).

137. The AKS also prohibits entities or persons from offering any form or payment or remuneration to induce a person "to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program" or "to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in party under a Federal health care program." *Id.* §§ 1320a-7b(b)(2)(A), (B).

138. As early as 1994, the Department of Health and Human Services Inspector General notified drug companies and others about improper practices such as alleged herein. In this Special Fraud Alert, the Inspector General specifically noted as improper payments to HCPs appearing to be made based on the volume of business generated by the HCP. *See* Department of Health and Human Services, Publication of OIG Special Fraud Alerts 59 Fed. Reg. 65372-01 (Dec. 19, 1994).

139. Therefore, Medicaid, Medicare, TRICARE, and other Federal Programs will not cover claims for prescription drug reimbursement that involve kickbacks of any kind. These provisions include not only express bribes or similar schemes, but also any payment by a drug company which has as a purpose an inducement to write prescriptions for a particular drug.

140. As is demonstrated throughout this Complaint, Eli Lilly employees violated the AKS through their dealings with Specialty Pharmacies and by establishing speaking programs where Physicians were paid to promote the off-label use of Forteo to other Physicians and to prescribe Forteo in their own practices.

E. Eli Lilly's False, Misleading, and Illegal Marketing of Forteo Caused the Submission of False and Fraudulent Claims to Federal Health Care Programs

141. Defendant Eli Lilly promoted off-label indications and durations of Forteo, knowing they were not eligible for reimbursement because the indication or dosage was neither listed on the drug reporting compendia or the relevant fiscal intermediary's Local Coverage Determination, nor was it included on Forteo's FDA-approved product labeling. Furthermore, Defendant Eli Lilly illegally promoted off-label uses without meeting the FDA requirements, and without resubmitting Forteo to the FDA testing and approval process. Thus, claims for reimbursement of off-label Forteo prescriptions fail to meet the eligibility requirements of Federal Programs. Eli

Lilly's off-label promotion of Forteo resulted in reimbursement by Federal Programs for numerous false and fraudulent claims.

142. Eli Lilly informed its sales representatives of the opportunities that Federal Programs provided for increasing sales of Forteo. Sales representatives were instructed that Medicare would begin paying for prescription drugs through Part D as of January 1, 2006. Sales representatives were also instructed by Eli Lilly of the various requirements for reimbursement through TRICARE and Medicaid, including formulary information on Forteo. In fact, Eli Lilly characterized Medicare's coverage of prescription drugs as a "good opportunity for Forteo."

143. Eli Lilly sales representatives were encouraged to leverage opportunities with Federal Program patients. For instance, on June 4, 2002, Relator [redacted] informed her District Manager, Greg Gerrald, that noted that one of the doctors in her territory at MUSC was "pulling up a query from their pt. [patient] database for all Medicare pts. [patients] over 65 who have not had a bone scan in 2 years. And, mailing and calling these pts. [patients] and letting them know of the risk of osteoporois [sic] and Medicare coverage for a Dexa scan." This information was reported up the Eli Lilly corporate chain of command and was encouraged by supervisors.

144. Beginning in 2002 and continuing until the present, Eli Lilly has caused numerous false and fraudulent claims to be submitted to Federal Programs due to their off-label and fraudulent marketing scheme. Since these claims were presented by thousands of entities all over the United States for which Relator [redacted] has no access, Relator [redacted] cannot identify all of these false claims for payment.

145. For example, upon information and belief, in 2006, approximately 679,004 prescriptions for Forteo were written and the cost of Forteo at the time was $600 per month. In 2006, approximately 11% of prescriptions were paid through Medicaid, 23% were written for

Dual Eligible enrollees, 29% were written for standard Medicare Part D beneficiaries, 6.9% were written for TRICARE enrollees, and 1.7% were written for patients enrolled in other Federal Programs. Because the total domestic revenue from Forteo prescriptions for 2006 was approximately $407,402,400, the amount of revenue generated from Federal Program reimbursements was approximately $291,700,118.40 (71.6% of the total revenue).

146. Upon information and belief, a great many of these claims processed through Federal Programs in 2006 were false and fraudulent claims under the False Claims Act due to Eli Lilly's unlawful promotion and marketing scheme.

147. Upon information and belief, similar percentages of claims were processed through Federal programs from 2007 to present (and prior to 2006 – excluding Dual Eligible and Medicare enrollees since Medicare did not begin reimbursing for prescription drugs until 2006).

148. The submission of these false and fraudulent claims to Federal Programs from 2002 to present caused Federal Programs to pay for and reimburse for numerous prescriptions for Forteo that would not have been presented for payment or reimbursement absent Eli Lilly's unlawful marketing practices

COUNT I
VIOLATION OF FALSE CLAIMS ACT, 31 U.S.C. § 3739, ET SEQ.

149. Relator [redacted] incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

150. This is a civil action for treble damages and penalties brought by Relator [redacted] on behalf of the United States of America against Defendant Eli Lilly under the False Claims Act, 31 U.S.C. §§ 3729(a)(1) and (2).

151. Defendant knowingly presented or caused to be presented false or fraudulent claims to the United States government for payment or approval in violation of, *inter alia*, 31 U.S.C. § 3729(a)(1).

152. Defendant knowingly made, used, caused, or caused to be used false or fraudulent records and/or statements, and omitted material facts, to induce the United States government to approve and pay such false or fraudulent claims paid in violation of, *inter alia*, 31 U.S.C. § 3729(a)(2).

153. Each prescription written as a result of Defendant's illegal marketing practices and/or illegal inducements represents a false or fraudulent record or statement. Further, each claim for reimbursement for such off-label and/or illegally induced prescription submitted to federal health insurance programs constitutes a false or fraudulent claim for payment.

154. The United States of America, unaware of the falsity of the claims and/or statements made by Defendant, and in reliance on the accuracy of these claims and/or statements, paid and continues to pay for claims that would not be paid but forth the illegal conduct.

155. As a result of Defendant's actions as set forth above in this Complaint, the United States of America has been, and continues to be, severely damaged.

COUNT II
UNJUST ENRICHMENT/DISGORGEMENT

156. Relator [redacted] incorporates herein by reference the preceding paragraphs of the Complaint as though fully set forth herein.

157. As a result of the acts set forth in this Complaint, Defendant Eli Lilly was unjustly enriched. The United States conferred benefits upon Defendant Eli Lilly by reimbursing false claims for Forteo and Defendant Eli Lilly knew of and accepted these benefits. Defendant Eli Lilly's retention of these benefits would be unjust in light of their fraudulent conduct.

158. Relator then claims the recovery of all monies by which Defendant Eli Lilly has been unjustly enriched, in an amount to be determined at trial, which should be paid to the United States.

WHEREFORE, Relator [redacted] prays for judgment against Defendant as follows:

A. Award the United States damages in the amount of three times the actual damages it sustained because of the false claims and fraud alleged within this Complaint, as provided by the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*;

B. Impose civil penalties of $11,000 for each and every false claim that Defendants presented to the United States and/or its agencies;

C. Grant permanent injunctive relief to prevent any recurrence of the False Claims Act for which redress is sought in this Complaint;

D. That Relator [redacted] be awarded the maximum amount allowed pursuant to the False Claims Act;

E. That Defendant be ordered to disgorge all sums by which they have been enriched unjustly by their wrongful conduct;

F. That judgment be granted for Relator [redacted] for all costs, including, but not limited to, pre- and post-judgment interest, court costs, expert fees, and all attorneys' fees incurred by Relator [redacted] in the prosecution of this suit; and

G. That Relator [redacted] be granted such other and further relief as the Court deems just and proper.

JURY TRIAL DEMAND

Relator [redacted] demands a trial by jury of all issues so triable.

Dated: July 19, 2012

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